GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4595
ANSWERED ON:12.08.2016
Quality Test
P. Shri Nagarajan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the medicines made by several Indian pharmaceutical companies have failed to qualify quality tests conducted recently by the Drugs Controller General of India (DCGI) and if so, the details thereof;

(b) the total number of drug manufacturing companies failed to qualify quality test and identified by DCGI, company-wise; and

(c) the action taken/proposed to be taken by the Government against these companies?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) to (c): The Drugs & Cosmetics Act, 1940 and Rules made thereunder are administered both by the Central Government through Central Drugs Standard Control Organisation (CDSCO) and State/UT Governments through respective Drug Controllers. As per data available with CDSCO, the percentage of 'Not of Standard Quality' and spurious/adulterated drugs are as below:

Year Samples picked by CDSCO Samples picked by State Regulators
Not of Standard Quality Spurious/
adulterated Not of Standard Quality Spurious/adulterated
2011-12 3.33 0.03 4.54 0.27
2012-13 2.80 Nil 4.03 0.11
2013-14 2.82 0.09 4.16 0.16
2014-15 3.35 Nil 4.98 0.11
2015-16 3.96 0.17 4.96 0.31

The percentage of 'Not of Standard Quality' drugs in the country are broadly comparable to percentage of NSQs in other countries. The Government has taken a series of steps to improve the quality of drugs in the recent past. These include:

â€¢ Risk based inspection of manufacturing facilities after training of officials from the regulatory structures and laboratories both from the Centre and the States together;
â€¢ Conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union;
â€¢ Conduct of training programmes for laboratory personnel of the State and Central laboratories to upgrade their analytical capabilities and skill sets;
â€¢ Undertaking a large scale nation-wide survey to determine the 'not of standard quality' drugs;
â€¢ Issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or not of standard quality;